

Operator's Manual



ATEC[®] Breast Biopsy and Excision System *Sapphire™* Unit

SUROS | COMPASSIONATE
TECHNOLOGIES[®]

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Covered by one or more of the following patents and other patents pending: 6,758,824 and 6,638,235.

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Precautions

Please read all contents of the Operator's Manual for your ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit prior to installation and operation. Follow all warnings and instructions as stated in this manual and retain for future reference. Physicians should inform patients about all potential risks and adverse events discussed in this manual with respect to the use of the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit.

As used below, the term “Suros™” means Suros Surgical Systems, Inc., a Delaware corporation. As used below, the term “ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit” means the ATEC *Sapphire*™ console unit and all available ATEC® Breast Biopsy and Excision System components, as more fully described in the Components section below (unless the context dictates otherwise).

- ❖ Should any object or liquid fall into the ATEC *Sapphire*™ console, unplug the console and have it checked by qualified personnel before operating it any further.
- ❖ Unplug the console from the electrical outlet if it is not to be used for several days or an extended period of time.
- ❖ Allow adequate air circulation around the console to prevent internal heat build-up. Do not place the console on surfaces or near materials that may block the ventilation openings.
- ❖ Do not install the console in a location near heat sources such as radiators or air ducts, or in a place subject to direct sunlight, excessive dust, mechanical vibration or shock.
- ❖ To keep the console looking new, periodically clean it with a soft cloth. Stubborn stains may be removed with a cloth lightly dampened with a mild detergent solution. Never use strong solvents or abrasive cleansers since these will damage the console casing. The console should only be cleaned after the power cord is disconnected from the power outlet and the console.
- ❖ Do not place the console on an unstable surface. The console may fall, causing serious injury and damage to the appliance. Quick stops, excessive force and uneven surfaces may cause the console to overturn.

Warnings and Cautions

Warnings

- ❖ **THE COMPONENTS OF THE ATEC® BREAST BIOPSY AND EXCISION SYSTEM: *SAPPHIRE*™ UNIT ARE FOR USE ONLY BY QUALIFIED MEDICAL PERSONNEL TRAINED IN THEIR USE AND APPLICATION.** Qualified medical personnel should perform a test of the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit prior to each procedure or prior to each time a new single patient use disposable is attached to the console.
- ❖ To prevent fire or shock hazard, do not expose the console to rain or moisture.
- ❖ To prevent shock hazard, do not use the console's polarized plug with a receptacle or other outlet unless the blades can be fully inserted to prevent blade exposure.

- ❖ Do not use the console's polarized plug with an extension cord.
- ❖ Use only disposables that are manufactured by Suros. Use of any other disposables may result in damage to the console and unintended injury to the patient or unacceptable clinical results and shall void any warranty provided by Suros herein.
- ❖ Only Suros-approved accessory equipment and components shall be used with the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit. Use of the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit with unauthorized accessory equipment and components shall void any warranty provided by Suros herein.
- ❖ All disposables associated with the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit are intended for single patient use and are not intended for resterilization and subsequent reuse. Dispose of all single patient use instruments after opening and use.
- ❖ **Do not resterilize any ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit single patient use instrument or accessory.** Resterilization may compromise the integrity and mechanical function of the instrument or accessory, which may result in unintended injury to the patient or unacceptable clinical results.
- ❖ **DANGER:** There is a small risk of explosion if the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit is used in the presence of flammable anesthetics or other explosive gases.
- ❖ The ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit console should only be opened or serviced by Suros or qualified personnel who have been trained and certified by Suros Surgical Systems, Inc.

Cautions

- ❖ Console not intended for use in the MRI suite.
- ❖ Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- ❖ Grounding reliability can only be achieved when the console is connected to an equivalent receptacle marked "Hospital Grade."
- ❖ The console should not touch other electrical equipment during use.
- ❖ The console can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the console does cause harmful interference to other devices, which can be determined by turning the console off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 - ☐ Reorient or relocate the receiving device.
 - ☐ Increase the separation between the equipment.
 - ☐ Connect the console to an outlet on a circuit different from that to which the other device(s) are connected.
 - ☐ Consult Suros for technical help.
- ❖ Damage to the power cord may cause a fire or shock hazard. When unplugging the power cord, please hold by the plug and remove it carefully. Do not damage or modify the console power cord.
- ❖ When the console is not being used, turn off all power switches and place the console in a location where it will not be damaged.

- ❖ Do not place the console on an unstable surface. The console may fall, causing serious injury and damage to the unit. Quick stops, excessive force and uneven surfaces may cause the console to overturn.
- ❖ Some ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit consoles may include settings specific to higher altitudes. Please contact Suros Customer Support or your distributor if you move your console to a significantly different physical address.
- ❖ If you are a Suros customer in the U.S. or in Canada, consult your Suros Sales Representative or Suros Customer Support if you cannot correct a problem using this Operator's Manual. If you are an international customer, please contact your distributor directly with questions, comments and/or technical service issues.

Symbols



The MR within a triangle is intended to alert the user that a component or components of the system are “MRI Conditional” and may be brought into an MRI suite.

Introduction

This manual is written for medical personnel who will be responsible for operating the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit. It is extremely important that the operator read and thoroughly understand the contents of this manual, be trained by a qualified applications specialist, and follow the instructions contained herein for reliable, safe and efficient operation of the product.

CAUTION: Federal law restricts this device to sale by or on the order of a physician pursuant to C.F.R. 801.109(b)(1).

ATEC® Users in the United States and Canada

All users of the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit in the United States and Canada should contact their Suros Sales Representative or the Suros Customer Service Department for questions, comments, and/or technical service issues.

International ATEC® Users

All international users of the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit should contact their distributor directly with questions, comments, and/or technical service issues.

Indications

- ❖ The ATEC® Breast Biopsy and Excision System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. The ATEC® Breast Biopsy and Excision System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedure.

Contraindications

- ❖ The ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit is for diagnostic use only and is NOT indicated for therapeutic use. The ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit is NOT intended to be used outside of the standards, specifications and limitations for the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit as outlined in this manual and other related materials.
- ❖ The ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit is contraindicated for those patients where increased risk or complications may be associated with biopsy based on the physician's judgment. Patients receiving anticoagulant therapy or who may have bleeding disorders may be at increased risk of procedural complications.

Notes on the MRI Environment

- ❖ The ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit may be used to perform biopsies under ultrasound, stereotactic or MRI guidance.
- ❖ The ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit console is **not** intended for use in the MRI suite. The ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit console must reside outside of the MRI suite.
- ❖ The ATEC® footswitch, ATEC® MRI handpiece and ATEC® Introducer Localization System are safe to use in the MRI suite.
- ❖ Suros offers a variety of disposable handpiece configurations. ***However, when performing MRI-guided breast biopsy procedures, an ATEC® MRI handpiece must be used. The ATEC® Introducer Localization System is available for localizing the area targeted for biopsy. The ATEC® MRI handpiece and ATEC® Introducer Localization System is specifically designed for use in the MRI environment.*** ATEC® handpieces designed for use with MRI guidance are compatible with the red receptacle marked “MRI” on the console.
- ❖ ATEC® handpieces designed for use with stereotactic (STX) and ultrasound (US) guidance are compatible with the red receptacle marked “US/STX” on the console.
- ❖ The particular handpiece selected for use with ultrasound or stereotactic guidance depends on user preference and the type of stereotactic system being used. Please refer to the **Disposable Component Selection** section of this manual for additional guidance.
- ❖ A complete list of ATEC® handpieces and other disposables suited for MRI, stereotactic or ultrasound-guided biopsy procedures is included in the **Components** section.

Components

Below is a list of available components for the ATEC® Breast Biopsy and Excision System: *Sapphire™* unit.

Capital Equipment (multiple patient use)

ATEC® Breast Biopsy and Excision System: *Sapphire™* unit

ATEC® Footswitch

ATEC® Power Cord

ATEC® Vacuum Line Assembly

ATEC® Stereotactic Adapter for use on stereotactic systems

Single Patient Use Disposable Components for Procedures Using Stereotactic or Ultrasound Guidance

ATEC® Handpiece

ATEC® Suction Canister

ATEC® Tissue Filters

ATEC® Remote Tissue Filter Adapter (RTFA)

The RTFA is for use with Lorad® upright stereotactic systems and Siemens stereotactic systems.

ATEC® Needle Guides

For use with stereotactic systems.

Single Patient Use Disposable Components for MRI-Guided Procedures

ATEC® MRI Handpiece

ATEC® Introducer Localization System

ATEC® Suction Canister

ATEC® Tissue Filters

Capital Equipment *(multiple patient use)*

	MRI Guided Biopsy Procedures	Ultrasound Guided Biopsy Procedures	Stereotactic Guided Biopsy Procedures
ATEC® Breast Biopsy and Excision System: <i>Sapphire™</i> unit	❖	❖	❖
ATEC® Footswitch	❖	❖	❖
ATEC® Power Cord	❖	❖	❖
ATEC® Vacuum Line Assembly	❖	❖	❖
ATEC® Stereotactic Adapter			❖

Single Patient Use Disposable Components

	MRI Guided Biopsy Procedures	Ultrasound Guided Biopsy Procedures	Stereotactic Guided Biopsy Procedures
ATEC® MRI Handpiece	❖		
ATEC® Introducer Localization System	❖		
ATEC® Handpiece		❖	❖
ATEC® Suction Canister with Lid	❖	❖	❖
ATEC® Tissue Filters	optional	optional	optional
ATEC® Remote Tissue Filter Adapter (RTFA)			optional
ATEC® Needle Guides			❖

Disposable Handpiece Selection by Catalog Number

Suros offers a variety of ATEC® handpiece configurations. As the chart below indicates, the specific handpiece selected depends on user preference (9GA vs 12GA cutting cannula) and the type of imaging equipment being used. Please note that Suros offers two specialized handpieces with a “petite” aperture for stereotactic and MRI-guided biopsy procedures. The standard petite handpiece (ATEC0912-12) for stereotactic-guided breast biopsy allows for breast compression to as little as 20mm. The ATEC *MRI Access*™ petite handpiece (ATEC0914-12MR) for MRI-guided breast biopsy features a hemispherical needle tip and allows for breast compression to as little as 16mm.

Please refer to the Suros Website at www.SurosSurgical.com for an updated list of disposable handpiece offerings.

ATEC® handpiece catalog numbers use the following number nomenclature:

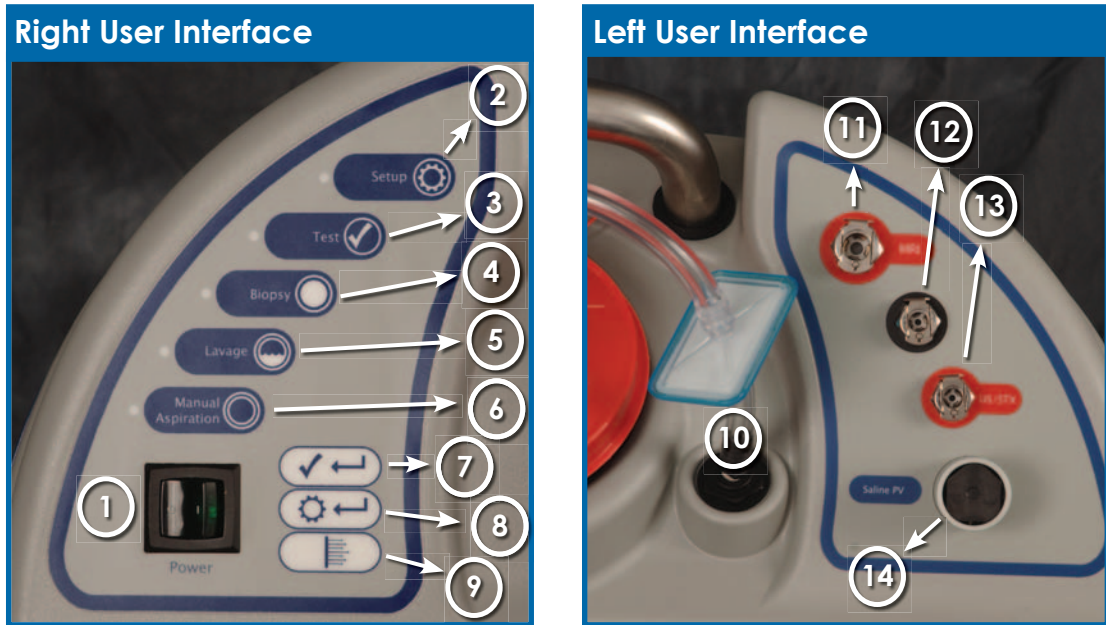
ATEC® Cutting Cannula Needle Gauge / Needle Length (cm) / Aperture Size (mm).

For example, an ATEC0912-20 handpiece is 12cm long, with a 9GA cutting cannula and a 20mm aperture.

ATEC® Compatibility Chart					
Equipment Type	Handpiece with 12GA Cutting Cannula	Handpiece with 9GA Cutting Cannula	Handpiece with Petite Aperture	ATEC® Stereotactic Adapter Model	Needle Guide
Lorad Prone Stereotactic Systems	ATEC1212-20	ATEC0912-20	ATEC0912-12	ATEC STX-1 or ATEC STX-2	NG09 NG12
Lorad Upright Stereotactic Systems <i>(An ATEC® Remote Tissue Filter Adapter should be used with each handpiece.)</i>	ATEC1212-20	ATEC0912-20	ATEC0912-12	ATEC STX-2	NG09 NG12
Fischer Stereotactic Systems <i>Frontal Approach</i>	ATEC1209-20	ATEC0909-20	ATEC0909-12	ATEC STX-Fischer or ATEC STX-2F	NG09F NG12F
Fischer Stereotactic Systems <i>Lateral Approach</i>	N/A	ATEC0914-20	Compression limit is not relevant	ATEC STX-Fischer or ATEC STX-2F	NG09F
Instrumentarium Stereotactic Systems	N/A	ATEC0914-20	Compression limit is not relevant	ATEC STX-2	NG09F
GE Stereotactic Systems <i>Lateral Approach</i>	N/A	ATEC0914-20	Compression limit is not relevant	ATEC STX-2	NG09F
GE Stereotactic Systems <i>Vertical Approach</i>	ATEC1212-20	ATEC0912-20	ATEC0912-12	N/A	NG09F NG12F
Siemens Stereotactic Systems <i>(An ATEC® Remote Tissue Filter Adapter should be used with each handpiece.)</i>	ATEC1212-20	ATEC0912-20	ATEC0912-12	ATEC STX-2	NG09F NG12F
Ultrasound Handheld Procedures	ATEC1212-20	ATEC0912-20	ATEC0912-12	N/A	N/A
MRI Procedures	N/A	ATEC0914-20MR plus ILS0914-20	ATEC0914-12MR plus ILS0914-12	N/A	Included in ILS

Console Controls and Functions

The console user interface panels include controls that enable the user to operate the ATEC® system and indicator lights that provide additional information about system status. A detailed description of each component on the user interface can be found below.



Console User Interface

1. **Power Switch** – Turns power to the console on or off: **On** = Illuminated **green** and “|”
Off = Not Illuminated and “O”
2.  **“Setup” Button** – This push button control allows for the self-priming of the system with saline. When placed in “Set Up” mode, the “Saline PV” (Pinch Valve) is opened and the vacuum is turned on, allowing insertion of the silicone section of the handpiece saline line into the pinch valve.
3.  **“Test” Button** – This push button control activates the handpiece through one test cycle. The system will return to “Biopsy” mode upon successful completion of one test cycle.
4.  **“Biopsy” Button** – When placed in “Biopsy” mode, the handpiece is ready for tissue acquisition.
5.  **“Lavage” Button** – When placed in “Lavage” mode, the “Saline PV” is opened and vacuum is turned on to irrigate and aspirate the biopsy cavity.
6.  **“Manual Aspiration” Button** – When placed in “Manual Aspiration” mode, the “Saline PV” is closed and the inner cutting cannula is retracted. In this mode, the user can vacuum the biopsy cavity by depressing the footswitch.
7.  **“Retest Handpiece” Indicator** – Does not illuminate under normal conditions. Flashes **red** when “Test” mode is not completed due to pressure failure. Refer to the Troubleshooting section for suggested steps to diagnose and correct a potential problem.
8.  **“Return to Setup” Indicator** – Does not illuminate under normal conditions. Flashes **red** when “Test” mode is not completed due to vacuum failure. Refer to the Troubleshooting section for suggested steps to diagnose and correct a potential problem.

9.  **“Vacuum Ready” Indicator** – Illuminates solid **green** when the console has achieved full vacuum. Flashes **green** when full vacuum is not achieved within the specified time frame. If this indicator flashes, refer to the Troubleshooting section for suggested steps to diagnose and correct a potential problem. *The footswitch will not enable the handpiece to function unless this indicator is illuminated solid **green**.*
10. **Vacuum Line Assembly** – This is clear tubing that is permanently attached to the console at one end. The other end has a **blue** connector that will attach to the ATEC® Suction Canister Lid at the port labeled “VACUUM.”
11. **Red “MRI” Handpiece Receptacle** – Attachment site for the MRI handpiece fitting with the **red** sleeve.
12. **Black Handpiece Receptacle** – Attachment site for the handpiece fitting with the **black** sleeve.
13. **Red “US/STX” Handpiece Receptacle** – Attachment site for the US/STX handpiece fitting with the **red** sleeve.
14. **“Saline PV” (Pinch Valve)** – Attachment site for the silicone tubing section of the handpiece saline line. Controls the flow of saline to the handpiece.

ATEC® Breast Biopsy and Excision System: Sapphire™ Unit Set Up

This section provides information on how to make all necessary connections to set up the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit.

The following connections will be explained:

- ❖ ATEC® Power Cord and Circuit Breaker
- ❖ ATEC® Footswitch
- ❖ ATEC® Vacuum Line Assembly
- ❖ ATEC® Handpiece

ATEC® Power Cord Connection and Circuit Breaker

CAUTION: Grounding reliability can only be achieved when this equipment is connected to an equivalent receptacle marked “Hospital Grade.” Check grounding continuity regularly.

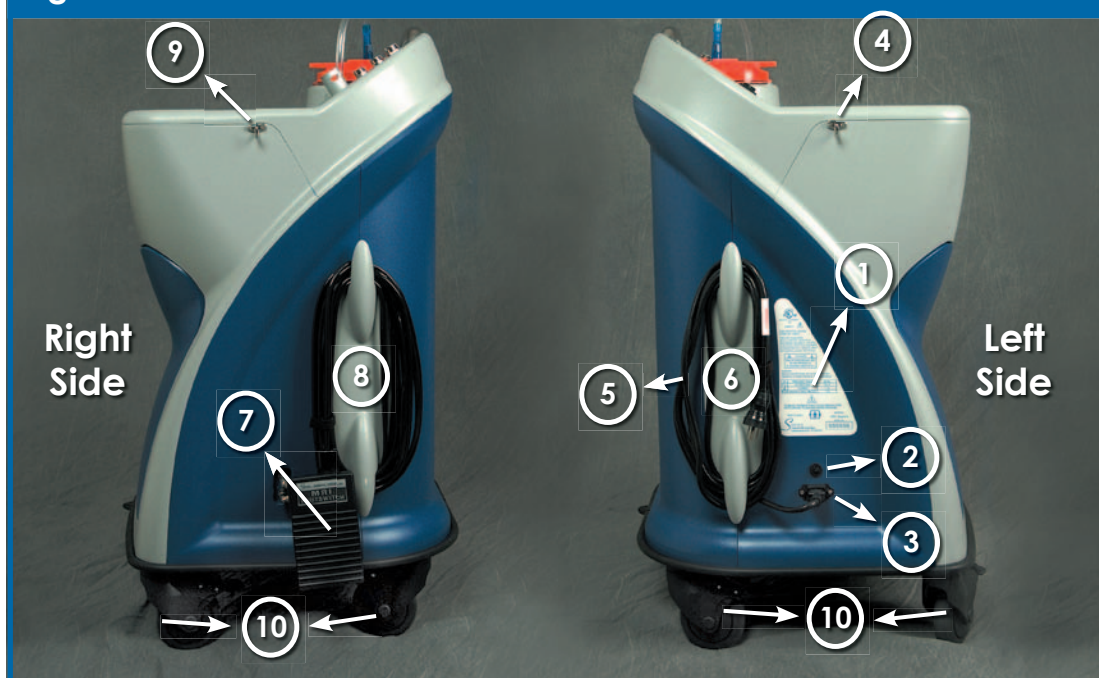
- ❖ Connect the ATEC® Power Cord Set into the power cord receptacle on the side panel, as shown in **Figure 1, left side**.

Note: The ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit console was designed to be used with the Hospital Grade Power Cord Set provided with the console. DO NOT use a different power cord with the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit. Using a different power cord may create an electrical and fire hazard. DO NOT, under any circumstances, remove the ground wire or ground plug from any power plug. DO NOT use an extension cord with this equipment. An adapter may be necessary depending on the outlet used.

The power cord will connect the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit to the facility power supply (electrical outlet). **Note:** This is the location of disconnect from the mains (electrical supply).

Note: Ensure that the power cord is in good condition. A damaged power cord can be an electrical shock hazard. When unplugging the unit, always grasp the plug at the insertion point and pull gently. **NEVER** pull on the cord to unplug the unit.

Figure 1: Console Electric Connections



1. **Ratings Chart** – Consult this chart if you need any information on the electrical ratings of the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit. This chart also contains the serial number of your ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit.
2. **Circuit Breaker** – Part of the AC Inlet. If the circuit breaker has been tripped, the black button will not be flush and a white dot will be visible. To reset, turn the unit off and allow for a one-minute “cool down” period before depressing the black button to restart the unit.
3. **AC Inlet** – Attachment site for the “Hospital Grade” plug and disconnect from the mains (electrical supply).
4. **Instructions Placard Hook** – Attachment site for the instructions placard.
5. **ATEC® Power Cord**
6. **ATEC® Power Cord Management Plate**
7. **ATEC® Footswitch** – Activates handpiece.
8. **ATEC® Footswitch Cord Management Plate**
9. **Saline Bag Hook** – Attachment site for saline bag (250cc recommended).
10. **Casters** – All four casters allow for a 360-degree swivel capability and have locking brakes to help hold the unit in place.

Footswitch Connection

- ❖ The footswitch is provided by Suros and should be attached to the right side of the console upon delivery.

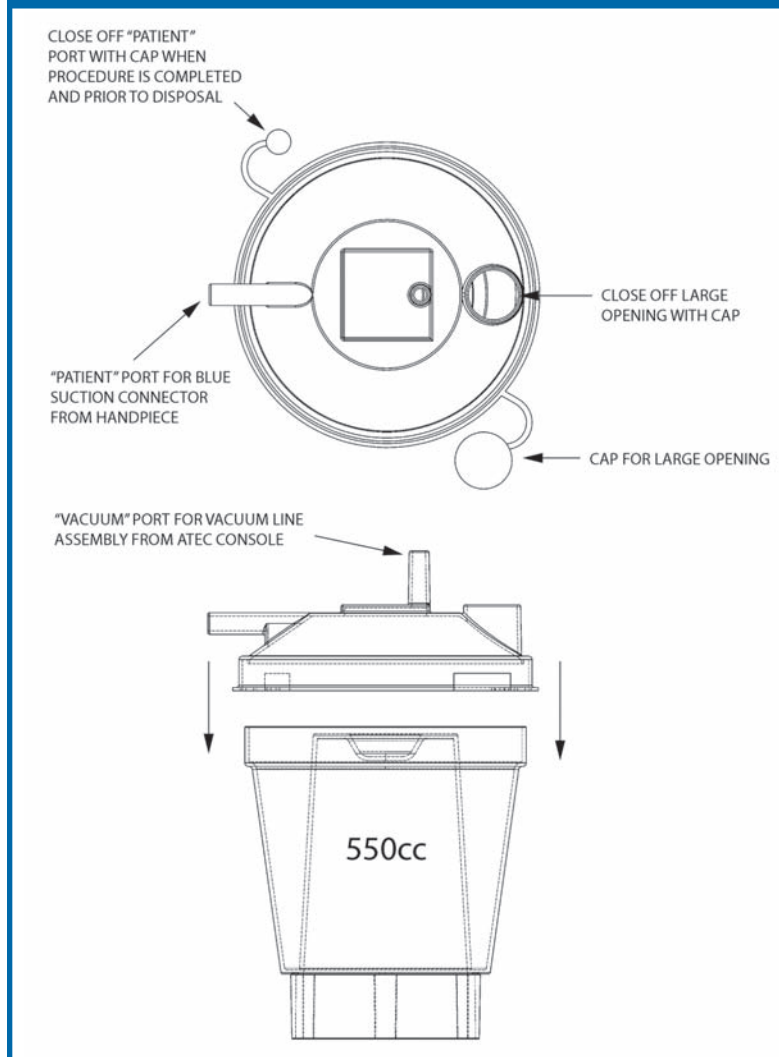
ATEC® Suction Canister Assembly

Once the console has been turned on, the system will generate its own vacuum.

The vacuum connections require that you use an ATEC® Suction Canister from Suros.

- ❖ Assemble the suction canister, as shown in **Figure 2**, and place in the canister holder on the top of the console in the canister seating area.
- ❖ Ensure that the lid and large port cap are secure and sealed to avoid vacuum leaks.
- ❖ Plug the vacuum line assembly on the console into the port labeled “VACUUM”  on the suction canister lid.

Figure 2: ATEC® Suction Canister



Note: The ATEC® Suction Canister is a single use product with a recommended maximum volume of 400cc.

Handpiece Connections

Using Aseptic Technique (refer to **Figure 3**):

- ❖ Peel open the saline bag, remove the cap and place the bag on the hook on the right side of the console.
- ❖ Peel open the sterile pack of the disposable handpiece and place tray on the top of the console. (Leave the protective sheath on handpiece tip.)
- ❖ Remove the terminal ends of the 4 lines from the handpiece tray.
 - ☐ Install the spike to the saline bag and insert the silicone section into the pinch valve labeled “Saline PV.”
 - ☐ Plug the **red** banded line into the receptacle on the console with the **red** ring.
 - ☐ Plug the **black** banded line into the receptacle on the console with the **black** ring.
 - ☐ Attach the **blue** suction fitting to the horizontal port marked “PATIENT” on the side of the suction canister lid.

Figure 3: Vacuum and Handpiece Assembly and Connections



ATEC® Breast Biopsy and Excision System: Sapphire™ Unit Check Out

- ❖ Power up the system by switching the **green** “Power” switch on the console to the “I” position. This switch will illuminate **green** when “on.”
- ❖ The power up or default mode is “Biopsy.”
- ❖ Select the “Set Up” mode. “Set Up” mode will prime the system and generate vacuum.

When the console is in “Set Up” mode, the “Vacuum Ready” light will illuminate when ample vacuum is achieved (see **Figure 4**). If ample vacuum is not achieved, the “Vacuum Ready” light will flash to alert the user to a possible problem. If the “Vacuum Ready” light flashes, refer to the **Troubleshooting** section of this manual for suggested steps to diagnose and correct a potential problem.

Figure 4: ATEC® Breast Biopsy and Excision System: Sapphire™ Unit Check Out



- ❖ Insert the silicone section of the saline tubing line into the pinch valve labeled “Saline PV” as shown in **Figure 5**.
- ❖ Verify the flow of saline into the aperture (mouth) and filter canister of the handpiece.
- ❖ The “Vacuum Ready” indicator will illuminate solid **green** to verify that vacuum has been attained.
- ❖ Select the “Test” mode.
- ❖ The handpiece will complete one test cycle. If the “Retest HP” or “Return to Set Up” indicator begins to flash, refer to the **Troubleshooting** section of this manual for suggested steps to diagnose and correct a potential problem.
- ❖ Upon completion of a successful test cycle, the handpiece will return to “Biopsy” and is ready for tissue acquisition.

Figure 5: Saline Pinch Valve Connection



Using the ATEC® Breast Biopsy and Excision System: *Sapphire*™ Unit

Using the System (MRI)

- ❖ When the console is in “Biopsy” mode, depressing the footswitch will activate the vacuum and operation of the handpiece.
- ❖ When the console is in “Lavage” mode, the user can automatically aspirate and irrigate the biopsy cavity. It is not necessary to depress the footswitch.
- ❖ When the console is in “Manual Aspiration” mode, depressing the footswitch allows the user to independently control aspiration without taking a tissue sample. This function may be used to vacuum or irrigate the biopsy cavity.

Additional operating instructions for an MRI-guided breast biopsy are outlined below.

Performing a Biopsy Using MRI Guidance

After setting up the ATEC® Breast Biopsy and Excision System per the steps outlined in this manual or in the ATEC® Easy-Guide Console Instructions Card, MRI-guided breast biopsy using the ATEC® may be performed by following the steps below:

- ❖ Once the area to be biopsied has been identified, prepare the area for biopsy utilizing standard facility techniques.
- ❖ Insert the sterile Needle Guide into the compression grid at the identified target area in the appropriate “cube.”
- ❖ Insert the Introducer Stylet that is hubbed to the Introducer Sheath. The depth stop on the Introducer Sheath is placed in the appropriate location according to the pre-determined “Z” axis.
- ❖ Insert the Introducer Sheath, with the Introducer Stylet, while rotating the sheath / stylet assembly into and through the Needle Guide to the depth stop, allowing for a pathway to the target area.
- ❖ Remove the stylet from the Introducer Sheath while leaving the Introducer Sheath in place.
- ❖ Insert the Localizing Obturator into the sheath.
- ❖ With MR image guidance, identify the location of the Localizing Obturator to the area to be biopsied.
- ❖ If location of Localizing Obturator is not accurate, reposition. If it is accurate, continue to step below.
- ❖ Remove Localizing Obturator from introducer sheath.
- ❖ Insert and hub the ATEC® handpiece into the Introducer Sheath and to the biopsy site in preparation for the biopsy to be performed.
- ❖ Once the biopsy is complete, remove the ATEC® biopsy handpiece, leaving the Introducer Sheath in place.
- ❖ After imaging to confirm acquisition of the target area and with the Introducer Sheath still in place, remove the patient from the MRI bore and place a biopsy site marker in the target area cavity to later identify the biopsy site.

Using the ATEC® Breast Biopsy and Excision System: *Sapphire™* Unit

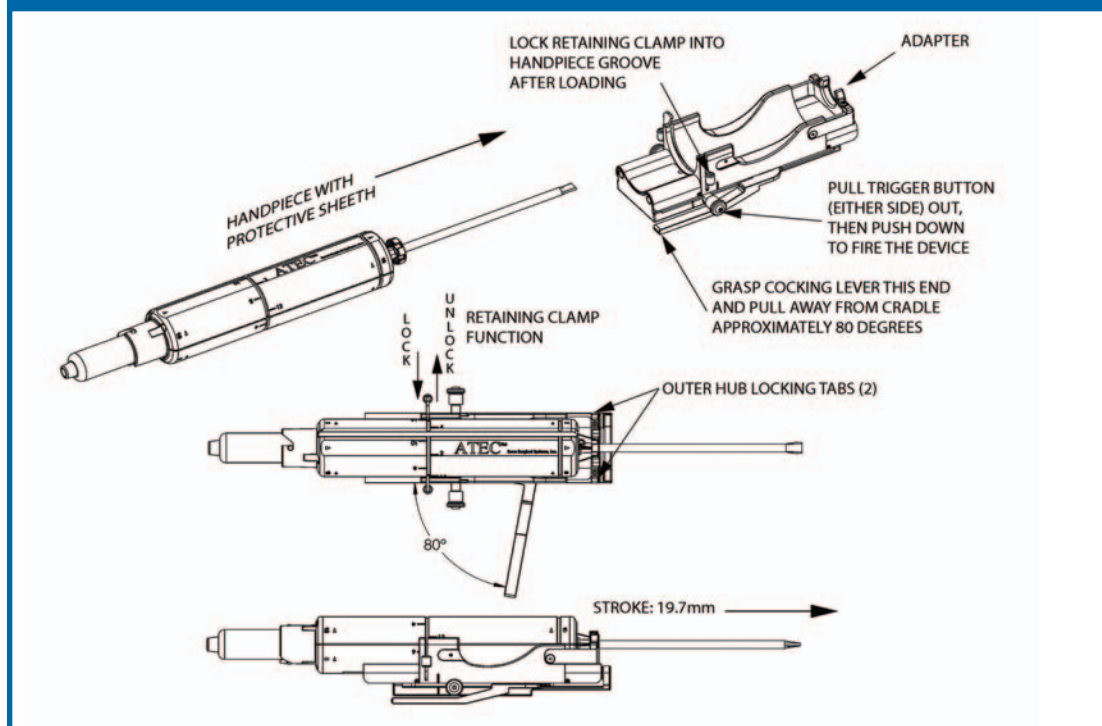
Using the System (Ultrasound or Stereotactic)

- ❖ When the console is in “Biopsy” mode, depressing the footswitch will activate the vacuum and operation of the handpiece.
- ❖ When the console is in “Lavage” mode, the user can automatically aspirate and irrigate the biopsy cavity. It is not necessary to depress the footswitch.
- ❖ When the console is in “Manual Aspiration” mode, depressing the footswitch allows the user to independently control aspiration without taking a tissue sample. This function may be used to vacuum or irrigate the biopsy cavity.

Additional operating instructions are required for a stereotactic biopsy and a stereotactic adapter must be utilized. Suros offers four stereotactic adapter models, which are depicted in Figures 6, 7, 8, and 9.

- ❖ **Figure 6: ATEC STX-1** (for Lorad prone stereotactic systems)
- ❖ **Figure 7: ATEC STX-2** (for Lorad upright, GE, Instrumentarium and Siemens systems, and for International Lorad prone systems)
- ❖ **Figure 8: ATEC STX-2F** (for International Fischer stereotactic systems)
- ❖ **Figure 9: ATEC STX-Fischer** (for Fischer stereotactic systems)

Figure 6: ATEC STX-1



Performing a Biopsy Using a Stereotactic Adapter

- ❖ With the clear protective sleeve covering the outer cannula, slide the ATEC® handpiece forward onto the stereotactic adapter until the ring on the front of the ATEC® handpiece engages with the guide ring on the front of the stereotactic adapter.
 - ❖ Lock the ATEC® handpiece into the stereotactic adapter by sliding the handpiece retaining clamp into the lock position.
 - ❖ Remove the protective sleeve covering the outer cannula.
 - ❖ If it is desirable to “rapid advance” the ATEC® handpiece into the target area, pull the cocking lever outwards about 80 degrees until there is no further forward movement. The cocking lever will return by spring action to its at-rest position.
- Note:** The stereotactic adapter can only be cocked if the handpiece retaining clamp is in the lock position.
- ❖ To “rapid advance” the ATEC® handpiece into the target area, pull the release/firing knob located on either side of the stereotactic adapter outward a minimum of 1/8” and then push the knob downward.
 - ❖ Immediately following the procedure, clean the stereotactic adapter as recommended in the **Cleaning** section of this manual.
 - ❖ For additional training or questions on specific stereotactic applications, please contact your regional Clinical Education Specialist or Suros Customer Support at 1-877-887-8767. If you are an international customer, please contact your distributor with questions.

Note: Complete training and understanding of your stereotactic device should be provided by your stereotactic system vendor.

Figure 7: ATEC STX-2

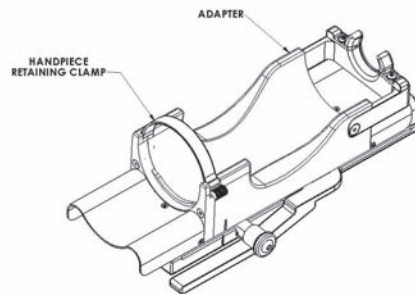


Figure 9: ATEC STX-Fischer

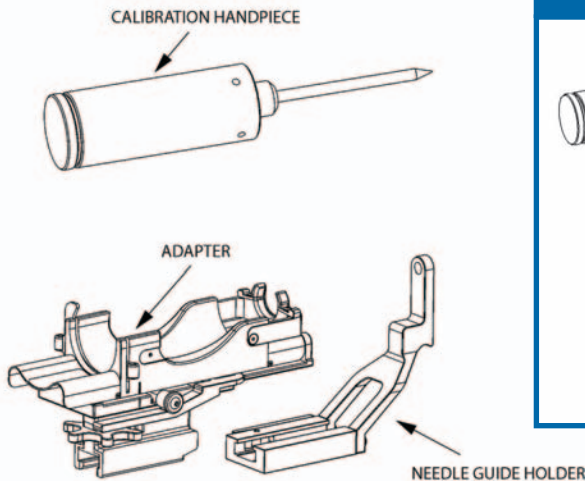
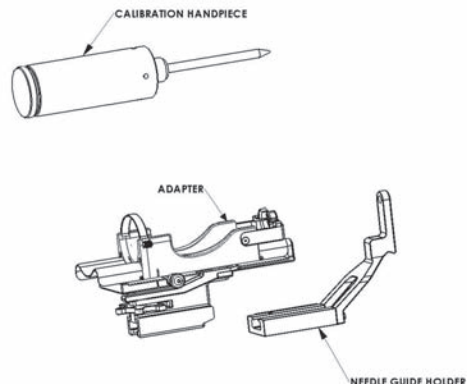


Figure 8: ATEC STX-2F

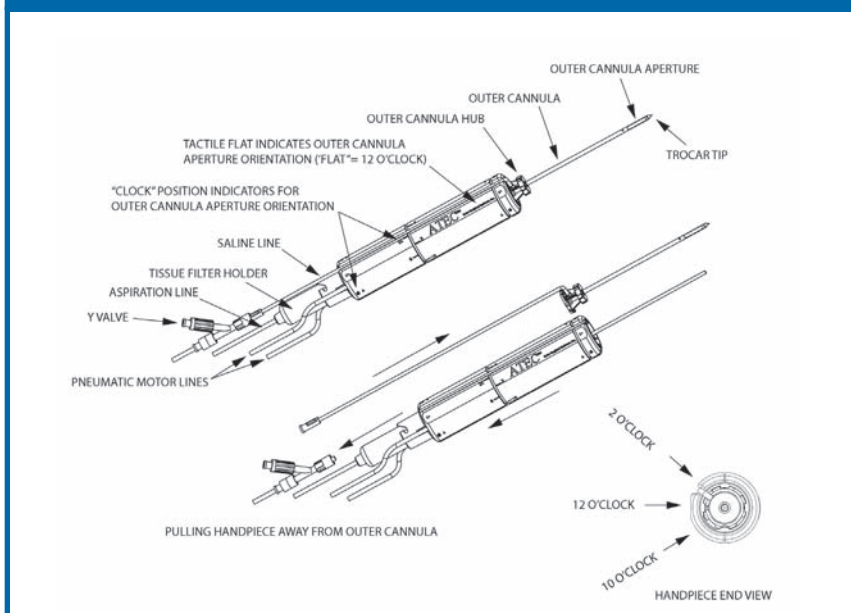


ATEC® Handpiece

Operating Instructions

- ❖ To rotate the aperture (sampling notch) on the outer cannula of the ATEC® handpiece, grasp the body of the ATEC® handpiece and rotate the ATEC® handpiece until the desired target area has been sampled. The clock dial on the ATEC® handpiece indicates the direction of the aperture. The number facing up indicates the location of the aperture within the patient. The arrow head indicates 12 o'clock as shown in **Figure 10**.
- ❖ To acquire tissue samples, select “Biopsy” mode, wait for a beep to sound, then press and hold the footswitch. Removing your foot from the footswitch will inactivate or stop the ATEC® handpiece after completing its current cycle.
- ❖ To lavage and vacuum the cavity, select “Lavage” mode. (It is not necessary to depress the footswitch.)
- ❖ To vacuum the cavity, select “Manual Aspiration” mode and depress the footswitch. Removing your foot from the footswitch will inactivate or stop vacuum to the ATEC® handpiece.
- ❖ To deploy a biopsy site marker, refer to the ATEC *TriMark*™ Instructions For Use (IFU).
- ❖ Suros Customers in the U.S. or Canada should contact their regional Clinical Education Specialist for compatibility and deployment of alternative biopsy site markers. International customers should contact their distributor.

Figure 10: ATEC® Handpiece



Note: There are many configurations of stereotactic systems available. The ATEC® stereotactic adapter configurations depicted in this manual may require a unique fitting to connect to your particular manufacturer / model. Please contact Suros Customer Support at 1-877-887-8767 if you believe this accessory, along with the appropriate instructions, was omitted. If you are an international customer, please contact your distributor directly with questions, comments, and/or technical service issues.

Troubleshooting

This section provides assistance with possible problems operating the ATEC® Breast Biopsy and Excision System: *Sapphire™* unit. Please consult the following information before contacting Suros or your distributor to make sure the problem is not a result of misinterpreting the operation of the system. If you are a Suros Customer in the U.S. or Canada, please consult your Suros Sales Representative or contact Suros Customer Support if you cannot correct a problem using this Operator's Manual. If you are an international customer, please contact your distributor directly with questions and/or comments.

Possible Problems Encountered During Set Up		
Problem	Possible Cause	Possible Remedy
Console will not turn on	1. Power cord is not plugged in at the console and/or wall outlet. 2. Console circuit breaker tripped.	1. Check power cord for proper engagement to console and wall outlet. 2. Reset breaker (see Figure 1).
Vacuum Ready indicator flashes or will not illuminate in "Set Up" mode	1. Protective sheath not on tip of handpiece cannula. 2. Suction canister lid not seated on canister bottom. 3. Suction canister cracked. 4. Large port on suction canister lid not capped with large plug. 5. Handpiece suction fitting not connected to the suction canister lid. 6. Handpiece suction fitting not connected to the correct port on suction canister lid. 7. Control console vacuum line not connected to the suction canister. 8. Spike on handpiece tubing is not inserted into saline bag. 9. Saline Y-Valve is disconnected. 10. Defective handpiece.	1. Replace protective sheath. 2. Seat lid to bottom. 3. Replace with new suction canister. 4. Cap large port with large plug. 5. Connect suction fitting to canister. 6. Connect to horizontal port marked "patient" on the side of the canister lid. 7. Connect the console vacuum line to the port marked "vacuum" on the suction canister lid. 8. Install spike into saline bag. 9. Reconnect Y-Valve. 10. Retain handpiece, record Lot Number, and contact Suros Customer Support or your distributor.
Return to Set Up indicator illuminates in "Test" mode	Same as above	Same as above
Retest Handpiece indicator illuminates in "Test" mode	1. Handpiece fittings plugged into control console incorrectly - check for red to red and black to black. 2. Defective handpiece.	1. Plug fittings into correct receptacles. 2. Retain handpiece, record Lot Number, and contact Suros Customer Support or your distributor.

Possible Problems Encountered During a Procedure

Problem	Possible Cause	Possible Remedy
No power: Power switch not illuminated	1. Power cord is not plugged in at the console and/ or wall outlet. 2. Console circuit breaker tripped.	1. Check power cord for proper engagement to console and wall outlet. 2. Reset breaker (see Operator's Manual Figure 1).
Poor quality biopsy cores or no cores	1. Reduced or no vacuum at tip of handpiece cannula. a. Suction canister lid not seated on canister bottom. b. Suction canister is cracked. c. Large port on suction canister lid not capped with large plug. d. Handpiece suction fitting not connected to the suction canister lid. e. Handpiece suction fitting not connected to the correct port on suction canister lid. 2. Inner cutting cannula not sharp. 3. Tissue filter occluded by blood. 4. Saline line not inserted to pinch valve. 5. Too much compression on the breast during a stereotactic procedure.	1. See a) through e) below. a. Seat canister lid. b. Replace suction canister. c. Cap large port on canister lid with large plug. d. Connect suction fitting to vacuum port marked "patient" on side of lid. e. Remove suction canister, replace with a new canister lid and bottom and place handpiece (blue) suction fitting on the port marked "patient." 2. Replace with new handpiece. 3. Replace tissue filter with a new filter. 4. Install saline line to pinch valve. 5. Reduce compression on breast.

Warranty

ATEC® Breast Biopsy and Excision System

Suros Surgical Systems, Inc. (“Suros”) warrants that the products which are the subject of this warranty (the “Products”) will perform in substantial conformity with the specifications for the Products which are described in operating manuals or instructions for use provided by Suros™ for the Products and that the Products will be free from defects in material and workmanship under normal use and proper operating conditions for the warranty period shown below, assuming the performance of ordinary preventative maintenance. Suros’ obligation under this warranty is limited to the repair or replacement, at its option, of any Product or part thereof, which has been returned to Suros for examination within the applicable time period described below and which examination confirms, to Suros’ satisfaction, such Product or part to be defective. This warranty does not apply to any Product, or part thereof, that has been: (1) adversely affected due to use with devices manufactured or distributed by persons not authorized by Suros, (2) repaired or altered by persons not authorized by Suros in a way so as to, in Suros’ judgment, affect its stability or reliability, (3) subjected to improper use, negligence or accident, or as to which the purchaser or user has failed to implement all updates or other instructions provided by Suros, or (4) used other than in accordance with the instructions for such Product established by Suros in the operating manuals or instructions for use provided by Suros or with standards generally accepted in the industry for similar products.

Products are warranted for the following periods beginning on the date of installation at the site of the customer who will use the Product or three months after delivery to the original purchaser, whichever is later:

- | | |
|---|-------------------------------|
| • Console unit (inclusive of power cord and footswitch) | One (1) Year, parts and labor |
| • ATEC® Stereotactic Adapter | One (1) Year, parts and labor |

Replacement parts supplied under this warranty shall be warranted for the remaining portion of the original warranty for the Product as to which the replacement part is utilized or a period of ninety (90) days from the date of installation by authorized personnel of the replacement part at the site of the customer who is using the Product, whichever period is longer.

This warranty is not applicable to single patient use devices associated with Suros ATEC® Breast Biopsy and Excision Systems.

THIS WARRANTY CONSTITUTES THE EXCLUSIVE REMEDY OF THE PURCHASER OR USER AND INCORPORATES THE ONLY WARRANTIES MADE BY SUROS AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED BY LAW, LEGISLATION OR OTHERWISE ARISING AND WHICH ARE HEREBY EXPRESSLY EXCLUDED, AND ALL SUCH WARRANTIES, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE AND FITNESS FOR ALL OTHER PURPOSES EXCEPT AS SPECIFICALLY PROVIDED FOR IN THE OPERATING MANUALS AND INSTRUCTIONS FOR USE PROVIDED BY SUROS, AS APPLICABLE, ARE HEREBY EXPRESSLY DISCLAIMED AND EXCLUDED. THIS WARRANTY SETS FORTH THE ENTIRE OBLIGATION AND LIABILITY OF SUROS AS TO THE SALE AND USE OF SUROS’ PRODUCTS. IN NO EVENT SHALL SUROS BE LIABLE FOR SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL EVEN IF SUROS IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGE, IT BEING UNDERSTOOD THAT THE PURCHASER OR CUSTOMER MAY CHOOSE TO MAKE ITS OWN INSURANCE OR OTHER ARRANGEMENTS TO REDUCE ANY SUCH DAMAGES IT MAY INCUR. IN ANY EVENT, SUROS’ LIABILITY FOR ANY DAMAGES UNDER THIS WARRANTY WILL NOT EXCEED THE TOTAL PURCHASE PRICE FOR THE PRODUCT. THIS WARRANTY DOES NOT AFFECT STATUTORY OBLIGATIONS WHICH MAY NOT BE DISCLAIMED OR LIMITED BY APPLICABLE LAW.

Suros neither assumes nor authorizes any other person to assume for it any liability in connection with the sale or use of any Products. Suros reserves the right to make changes to Products built and/or sold by it at any time without incurring any obligation to make the same or similar changes on Products previously built and/or sold.

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Indiana, United States of America. Any disputes arising under this warranty must be brought exclusively in the relevant federal or state district courts located in Indianapolis, Indiana, USA.

ATEC and Suros Compassionate Technologies are trademarks or registered trademarks of Suros Surgical Systems, Inc. All rights reserved.

Service and Maintenance

Suros offers a variety of Extended Service Protection and Preventive Maintenance options. For additional information, please visit the Suros website at www.SurosSurgical.com or contact your Suros Sales Representative, Suros Customer Support, or your distributor.

If you believe your ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit requires service or repair, please contact Suros Customer Support at 1-877-887-8767. 24-hour phone support is available at 1-800-780-9303.

ATEC® Users in the United States and Canada

All users of the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit in the United States and Canada should contact their Suros Sales Representative or the Suros Customer Service Department for questions, comments, and/or technical service issues.

International ATEC® Users

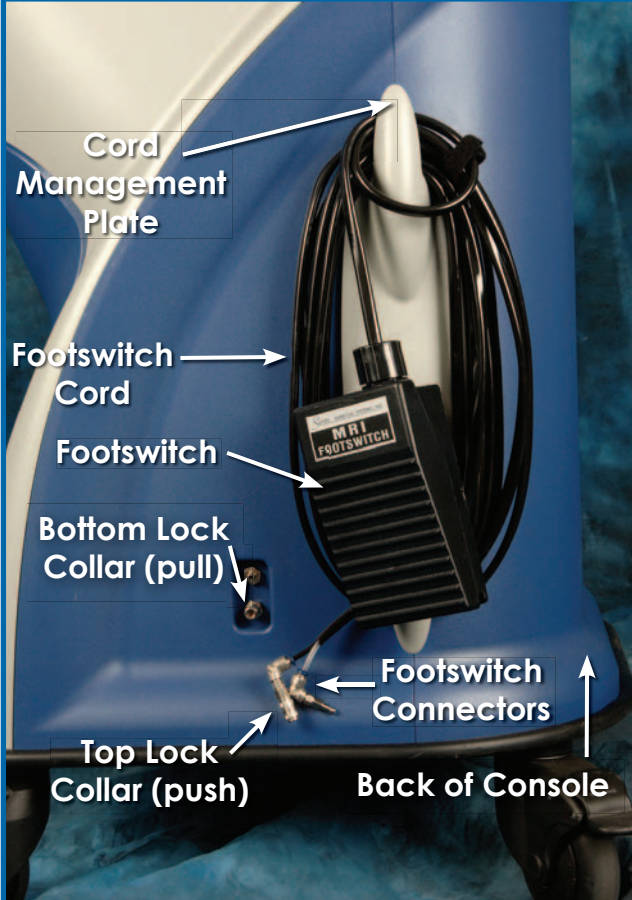
All international users of the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit should contact their distributor directly with questions, comments, and/or technical service issues.

Recommended Maintenance Schedule		
Activity	Frequency	Action
Inspect footswitch cord	Weekly	Verify that the 90° connectors are facing toward rear of the console. Verify that the footswitch cord is wrapped in the counterclockwise (CCW) direction around the cord management plate. Visually inspect the exposed 1.5" black and clear sections of tubing located between the footswitch connectors and the footswitch cord sheath for kinking.
Inspect vacuum line assembly	Weekly	Visually inspect for fluid or moisture in the tubing or any discoloration to the white side of the in-line hydrophobic filter.
Inspect power cord	Quarterly	Visually inspect for cuts and damage to outside cover and strain relief.
Test current leakage	Annually	Verify current leakage is less than 300 microamps.
Test power cord resistance	Annually	Verify power cord resistance is less than 500 milliohms.

The ATEC® Breast Biopsy and Excision System: *Sapphire™* unit includes several external components which can be replaced in the field. These external components include:

- ❖ ATEC® Footswitch Assembly
- ❖ ATEC® Vacuum Line Assembly
- ❖ ATEC® Power Cord

The following photos or diagrams noted on pages 23-25 offer specific replacement instructions for the external components of the console unit referenced above.

Field Replaceable Items	
Item	Instructions
Footswitch Assembly 	Removal (with the console powered off) 1) Completely unwrap and remove footswitch cord from cord management plate. 2) Disconnect upper and lower footswitch connectors by pulling out the top lock collar and pushing in the bottom lock collar. Once disconnected, place footswitch in Suros box and return to Suros for evaluation. Installing new footswitch assembly (with the console powered off) 1) Connect footswitch connectors so that the connectors point toward the back of the console. 2) Wrap the footswitch counterclockwise around cord management plate. Verification of Installation 1) Turn console power on. 2) You will hear the console beep; it will then default to the biopsy mode. 3) Plug the tip of the vacuum line assembly with thumb or finger. 4) Depress footswitch pedal and hold until solid green vacuum ready light is acquired. 5) Check for solid green vacuum ready light, the console audible beep at the end of each cycle and cycling of the pinch valve. 6) Release footswitch pedal and verify that the solid green vacuum light turns off and cycling stops.

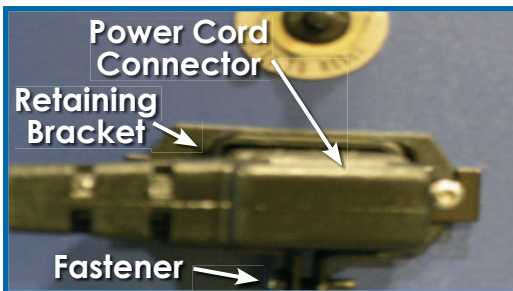
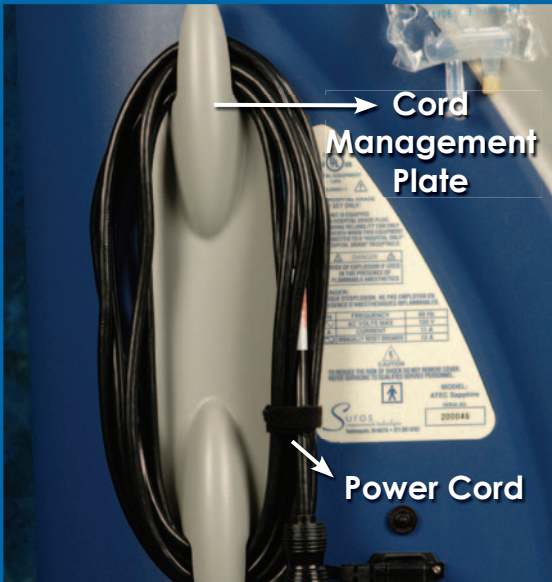
Field Replaceable Items (cont.)

Item	Instructions
Vacuum Line Assembly 	Removal (with the console powered off) 1) Locate the white lock collar where the vacuum line assembly attaches to the console. 2) Lift up on the vacuum line assembly approximately one-eighth inch, exposing a gap between the white collar and black barb base. 3) Insert a small slotted screwdriver into the gap created, then press and hold down the white collar. 4) While holding down the white collar, pull the vacuum line assembly up and out of the vacuum line assembly connector. Installation (with the console powered off) 1) Press the new vacuum line assembly into the vacuum line assembly connector. 2) Pull up to verify that it has locked into the connector. The vacuum line assembly will have a small amount of vertical movement, but should not pull free of the connector. Verification of Installation 1) Turn console power on. 2) You will hear the console beep; it will then default to the biopsy mode. 3) Plug the tip of the vacuum line assembly with thumb or finger. 4) Press the set-up button on the console. 5) Verify that the solid green vacuum ready light is illuminated, indicating that the system is functioning properly.

Field Replaceable Items (cont.)

Item

Power Cord



Instructions

Removal (with the console powered off)

- 1) Unplug console power cord from wall outlet.
- 2) Completely unwrap and remove power cord from cord management plate.
- 3) With #1 Philips screwdriver, loosen fastener located on bottom of retaining bracket.
- 4) Disconnect power cord connector from power receptacle.

Installation (with the console powered off)

- 1) Firmly and completely insert power cord connector into power receptacle.
- 2) With #1 Philips screwdriver, tighten fastener located on bottom of retaining bracket.

Verification of Installation

- 1) Plug power cord into wall outlet.
- 2) Turn console power on.
- 3) Verify console powers on, beeps and defaults to the biopsy mode.
- 4) Unplug power cord from wall outlet and wrap clockwise around cord management plate.

Cleaning Instructions

This section provides instructions on how to clean components of the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit. **WARNING:** Single patient use disposable items are not intended for reuse and should not be cleaned or resterilized.

ATEC® Breast Biopsy and Excision System: *Sapphire*™ Unit

To clean the ATEC® Breast Biopsy and Excision System: *Sapphire*™ unit console, disconnect from electrical power source. Periodically clean using a soft, damp cloth and mild detergent. Wipe dry. **Do not immerse in water!**

ATEC® Footswitch

Clean the ATEC® Footswitch thoroughly with mild detergent and wipe dry. **Do not immerse in water!**

ATEC® Stereotactic Adapter

Follow these instructions to clean the ATEC® stereotactic adapter:

1. Upon completion of the biopsy procedure, **immediately** rinse with **warm** water.
2. Spray adapter with a cleaner.
3. Rinse with **warm** water.
4. Wipe dry with cloth or paper towel.
5. Cycle hub retaining clamps, handpiece retaining clamp, cock and fire adapter (see **Figure 11**).
6. Re-clean the ATEC® stereotactic adapter if any component does not perform properly.



The ATEC STX-1 (left) and the ATEC STX-Fischer with bracket (right).

!Caution!

The following cleaning products are **not recommended** as they may damage the black self-lubricating coating or other exposed components of the ATEC® stereotactic adapter:

- ❖ Bleach-based cleaning agents
- ❖ Hydrogen Peroxide
- ❖ Any cleaner / disinfectant with a pH of less than 4 or greater than 10.

Note: Precise Hospital Foam Cleaner Disinfectant is an acceptable cleaning product for the ATEC® Stereotactic Adapter. Precise disinfectant may be ordered from Caltech Industries at (800) 234-7700.

Owner's Record

ATEC® Breast Biopsy and Excision System: *Sapphire™* Unit

The serial number of your **ATEC® Breast Biopsy and Excision System: *Sapphire™* unit** is located on the panel on the left side of the console. Record this number in the space provided below. Refer to this serial number whenever you contact Suros Customer Support or your distributor regarding your ATEC® Breast Biopsy and Excision System: *Sapphire™* unit.

Model Number: ATEC® Breast Biopsy and Excision System: *Sapphire™* Unit

Serial Number: _____

ATEC® Stereotactic Adapter

The serial number of your **ATEC® stereotactic adapter** is located on the bottom of the adapter. Record this number in the space provided below. Refer to this serial number whenever you contact Suros Customer Support or your distributor.

Model Number: (check one)

- ☐ **ATEC STX-1** (for Lorad prone stereotactic systems)
- ☐ **ATEC STX-2** (for Lorad upright, GE, Instrumentarium and Siemens stereotactic systems, and for International Lorad prone systems)
- ☐ **ATEC STX-2F** (for International Fischer stereotactic systems)
- ☐ **ATEC STX-Fischer** (for Fischer stereotactic systems)

Serial Number: _____

Specifications

ATEC® Breast Biopsy and Excision System: Sapphire™ Unit



	120V/60 Hz Model	240V/50 Hz Model
Size	25 in. Wide (63cm) 37 in. High (93cm) 21 in. Deep (53cm)	25 in. Wide (63cm) 37 in. High (93cm) 21 in. Deep (53cm)
Footprint (Width x Depth)	525 in ² (3400 cm ²)	525 in ² (3400 cm ²)
Weight	100 lbs. (45kg)	100 lbs. (45kg)
Maximum Power	1320W	1200W
Voltage	120V AC	240V AC
Frequency	60 Hz	50 Hz
Maximum Current	11 A	5 A
Fuse	12 A, Breaker	6 A, Breaker
Power Cord Length	15 ft. (5m)	15 ft. (5m)
Vacuum Generated	28"Hg (71cmHg) at sea level	28"Hg (71cmHg) at sea level

ATEC® Footswitch – MRI Compatible

Size	6 in. (16cm) Long 4 in. (9cm) Wide 2 in. (5cm) High
Weight	1 lb. (0.5kg)
Tubing Length	20 ft. (6m)

ATEC® Handpiece

Handpiece Size	1.6 in. (4cm) diameter x 10 in. (26cm) long
Weight	7 oz. (204g)
Needle Length	4 in. (9cm); 5 in (12cm); 6 in. (14cm)
Outer Cannula Diameter	12g – 0.106 in. (3mm); 9g – 0.146 in. (4mm)
Inner Cannula Diameter	12g – 0.079 in. (2mm); 9g – 0.118 in. (3mm)
Aperture Length	0.787 in. (20mm); 0.472 in. (12mm)
Tubing Set Length	15 ft. (5m) for US/STX handpiece 20 ft. (6m) for MRI handpiece
Sterilization	Gamma Irradiation

Storage and Transport Environmental Requirements

An ambient temperature of -29 degree to +60 degree Celsius

A relative humidity range of 30% to 85% excluding condensation

An atmospheric pressure range of 500hPa to 1060hPa

Equipment Operating Environmental Conditions

An ambient temperature of +15 degree to +40 degree Celsius

A relative humidity of 30% to 75%

Operating altitude: less than or equal to 3,657 meters above sea level

Classification



Type of protection against electric shock: Class I

Degree of protection against electric shock: Type BF

Degree of protection against the ingress of water: Ordinary

Mode of Operation: Continuous

More Information

For product availability, labeling limitations and more information, contact your Suros Sales Representative or call Suros Customer Support toll free at 877-887-8767. If you are an international customer, please contact your distributor for more information. Product information can also be found on the Suros website at www.SurosSurgical.com.

Important Contact Information

ATEC® Breast Biopsy and Excision System: *Sapphire™* Unit

Suros Sales Representative

Name: _____

Phone: _____

Email: _____

Suros Clinical Education Specialist

Name: _____

Phone: _____

Email: _____

Suros Customer Support
CustomerSupport@SurosSurgical.com
1-877-887-8767

Distributor Information

Name: _____

Phone: _____

Email: _____

Country: _____



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